



JIM GIBBONS
Governor

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

MICHAEL J. WILLDEN
Director

CHARLES DUARTE
Administrator

DRUG USE REVIEW (DUR) BOARD

Minutes
July 22, 2010

Grant Sawyer Office Building
555 E. Washington Avenue Room 4401
Las Vegas, Nevada 89416

Nevada State Legislature Building
401 So. Carson Street, Room 3137
Carson City, Nevada 89701

Committee Members Present:

Las Vegas: Paul Oesterman, Pharm.D.; James Marx, MD

Reno: Keith Macdonald, R.Ph.

Call-In: David England, Pharm.D

Absent: William Evans, MD; Steven Rubin, MD; Chris Shea, Pharm.D

Others Present:

DHCFP:

Las Vegas: Gabriel Lither; Deputy Attorney General

Reno: Coleen Lawrence, Chief, Program Services; Jennifer Matus, Pharmacy Program Specialist

Magellan Medicaid Administration:

Las Vegas: Rob Coppola Pharm.D, Program Director; Paula Townsend Pharm.D; Clinical Manager; Dave Wuest R.Ph., Clinical Manager; Shirley Hunting

Reno: Judy Lafleur, Kim Teixeira

Others:

Las Vegas: Anne Marie Licos-MedImmune; Jim Wilkes-Calloway Labs; Lori Howarth-Bayer; Jane Stephen-Allergan; Dev Vinson-MedImmune; Sandy Sierawski-Pfizer; Daniel Bay-Abbott; Dawn Conell-NHI; Jerry Gomez-Calloway Labs

Reno: Irene Camerino-Forest

i. Call to Order and Roll Call

Chairman Paul Oesterman called the meeting to order at 12:57 p.m.

Coleen Lawrence announced that former Nevada State Governor Kenny Guinn passed away this morning. Governor Guinn served from 1999 to 2007.

ii. Discussion and Approval of June 3, 2010 Minutes

MOTION: James Marx motioned to accept the June 3, 2010, minutes as presented.

SECOND: Keith Macdonald

VOTES: Unanimous

MOTION CARRIED

iii. Status Update by DHCFP

a. Program Updates

Coleen Lawrence said that the State is recruiting for an additional member for the DUR Board. She asked to be contacted if current members would like to serve another term and/or would like to provide recommendations for potential new members. Her office will be contacting members and working with those who wish to be reappointed. Due to budget restrictions, videoconferencing of the meetings will be utilized for future meetings.

Keith Macdonald stated that his wife has accepted a position with DHCFP and asked Gab Lither if this would be considered a conflict. Ms. Lawrence added that the position is with the Healthcare Reform Unit which is under a different reporting structure. Mr. Lither stated that this does not appear to be a conflict and Ms. Lawrence agreed.

iv. Nevada Medicaid Drug Utilization Review Annual Report Federal Fiscal Year 2009

a. Presentation by Magellan Medicaid Administration of the Nevada Medicaid Drug Utilization Review Annual Report

Dr. Townsend provided a summary of the report.

ProDUR: Therapeutic duplication generated the greatest number of alerts sent to pharmacies followed by drug-age conflicts (geriatric and pediatric combined) and drug-drug interactions. Paid claims that were reversed and not resubmitted resulted in a total cost avoidance of approximately \$34,435,677.

RetroDUR: 3,600 profiles were reviewed resulting in about 1,700 being selected for intervention. About 2,800 providers lettered. Provider response remains stable at 15%. The overall estimated cost savings was approximately \$100,000. The goal of the RetroDUR program is safety and compliance and not necessarily cost savings.

Drug Spend: The number of recipient utilizers per month increased by 6.6% (vs 2008) compared to a 5.6% increase in 2008 (vs 2007). The average payment per user per month decreased by 1.23% in 2009; in 2008 it had increased by 5.6%. Overall expenditures increased by 5.25% which is less than the rate of increase from the previous fiscal year of 11%.

Top Ten Therapeutic Classes Ranked by Total Payment Amount: Antipsychotics continue to rank highest with an increase in spend of 4.77%; analgesic narcotics surpassed the anticonvulsant class this year with an increase of 13.35% compared to a smaller increase of 3.9% in 2008. The shift between narcotics and anticonvulsants is due to the number of expensive anticonvulsants entering the generic market; anticonvulsant claims have not decreased. The rate of increase for Synagis®, the antiviral monoclonal antibody for prevention of RSV in infants (therapeutic class W5D), was twice that observed in the previous year (22% vs 9%). Insulin continues to rise at a high rate which is driven by the increase in newer and expensive insulin products as well as a significant increase in prescription count for this class. Compounded prescriptions dropped off the top ten list because pharmacies had been submitting claims for antihemophilic factor, a high dollar product, and other miscellaneous non-compounded products as compounds which skewed the data. Magellan conducted extensive re-training and these submission errors were corrected. As a result, antihemophilic factor payments increased and compounds dropped off.

Clinical PA Requests: The CNS stimulants and proton pump inhibitors (PPIs) remain the most frequently requested drugs requiring a PA. These two classes account for over two-thirds of clinical PA requests. 95% of CNS stimulant requests were approved; 82% of PPI requests were approved which is down from the previous year. The drug with the lowest approval rate is Lidoderm® at 8% reflecting the high off-label use; PA criteria are for labeled indication of the product.

Ms. Lawrence provided background information about the annual report. The Code of Federal Regulations, as a duty for the DUR Board, requires the annual submission of this

drug use review report. The template for the report is set by the Centers for Medicare & Medicaid Services (CMS). Next year CMS will be utilizing a new template.

b. Public Comment

Sandy Sierawski, Pfizer, stated that a copy of the report was not provided as a public handout and asked if there is access to the report.

Ms. Lawrence replied that the report is in draft form and will be available once it has been finalized.

c. Discussion and Action by Board to Approve Nevada Medicaid Drug Utilization Review Annual Report

MOTION: David England motioned to approve the annual report as presented.

SECOND: James Marx

VOTES: Unanimous

MOTION CARRIED

v. Review of Prescribing/Program Trends

a. Top 10 Therapeutic Classes (by Payment and by Claims)

Dr. Townsend presented the report for second quarter 2010, noting that the antihemophilic factors increased by 204% due to three patients that had catastrophic events requiring large doses. Total dollars in the anticonvulsant class has decreased, however, claims have increased by 3% which indicates a move to generic products. Antipsychotic claims continue to increase.

Dr. England asked if there is a correlation between pain and anticonvulsants since some can be used for pain. Dr. Townsend responded that this was discussed at last month's meeting and Magellan's biostatistician is working on a report which will provide utilization data of anticonvulsants by ICD-9 code and concurrent use of narcotic analgesics with anticonvulsants. The report will be presented at a future meeting. Also discussed at the last meeting was the increase in the claims count of skeletal muscle relaxants. This is being analyzed to determine what may be driving the trend and will be presented at a future meeting.

b. Top 50 Drugs (by Payment and by Claims)

Dr. Townsend presented the report for second quarter 2010.

Dr. Oesterman noted that there was a significant drop in hematinics and asked if there is any indication of a reason. Dr. Townsend stated that it may be a reclassification of the products and will research the class and provide a report to the Board.

Dr. Oesterman pointed out that carisoprodol is ranked seventh on the top 50 claim count report and felt it may be of interest to look at that to determine usage such as extended duration that this product is being used.

c. Program Trends

Dr. Townsend referred the committee to the data contained in the annual report.

vi. Concurrent Drug Utilization Review (ProDUR)

a. Review of Q2 2010

Dr. Townsend presented ProDUR reports for second quarter 2010, noting that the quarterly report is consistent with the information presented with the annual report.

Dr. Oesterman asked for examples of drug-to-gender claims denials. Dr. Townsend replied that some are various types of oral contraceptives (male estrogen claims); female claims for sildenafil or testosterone, etc. Dr. Coppola added that drug-to-gender edit examples are included in the annual report.

vii. Retrospective Drug Utilization Review (RetroDUR)

a. Review of Responses

Dr. Townsend reviewed the RetroDUR Letter Response Report by Response Code for first quarter 2010.

b. Status of Previous Quarter

Dr. Townsend reviewed the RetroDUR Summary Report of new reviews and re-review profile criteria and letters sent for first quarter 2010.

c. Status of Current Quarter

Dr. Townsend reviewed the RetroDUR Summary Report of new reviews and re-review profile criteria and letters sent for second quarter 2010, noting that the second quarter is still in data collection mode.

d. Public Comment

No comment.

e. Discussion and Action by Board for Future Criterion Selection

Dr. Townsend stated that, as discussed at the previous meeting, the Board is being asked for their input for future profile runs. Criteria can be selected based on the exception reports presented. The Board may also suggest criteria that may not be listed in the report. Dr. Townsend referred to the reports and suggested that due to the large number of exceptions (3,000), a review for non-compliance of antihypertensives, which can lead to MI, stroke, and other long term complications, be conducted. Other suggestions included a profile review of proton pump inhibitor duplication with H2 receptor antagonists and triptans interacting with SSRIs.

Keith Macdonald recommended review of tramadol utilization with the initial review to include straight claims numbers.

Dr. England suggested a review of tramadol and anticonvulsants which can aggravate or cause seizures.

Dr. Marx supported a review of tramadol utilization particularly or in conjunction with SSRIs, which can increase the likelihood of seizures more so than over utilizing tramadol, as well as triptans in conjunction with SSRIs. He felt that a review of tramadol with SSRIs would be more valuable than triptans with SSRIs which is more obscure.

Dr. Townsend summarized the recommendations for review: utilization report of PPI duplication with H2 receptor antagonists; utilization of tramadol, tramadol with anticonvulsants utilization and tramadol with SSRIs.

Dr. Oesterman stated that he interested in compliance particularly with maintenance medications such as glycemic and antihypertensive therapies.

MOTION: James Marx motioned for future profile runs to include a review of PPI duplication with H2 receptor antagonists, utilization of tramadol, tramadol with anticonvulsants and tramadol with SSRIs; and patient compliance report for glycemic and antihypertensive therapies

SECOND: Keith Macdonald

VOTES: Unanimous

MOTION CARRIED

viii. Update and Presentation on Dispense as Written (DAW = 1) Edit

a. Public Comment

No comment.

b. Discussion by Board

Dr. Townsend stated that the edit for claims submitted with the DAW-1 requiring a PA for a brand product when there is a generic available went into effect on May 13, 2010. To meet the criteria for approval, the patient must experience either: a. therapeutic failure or adverse reaction to the “A” rated generic; b. experience an allergy to one of the components of the generic and has tried a second manufacturer’s generic; or c. the prescriber states that in their opinion, transition to a generic alternative would represent an unacceptable risk to the patient. In reasons a and b (failure or allergy), the prescriber must state that a MedWatch form has been submitted to the FDA reporting the failure, adverse reaction or allergy to the generic product. She presented a summary of PAs requested noting that it is too early to determine if prescribing trends have changed. She also presented a table summarizing the number of PA requests, denials, approvals, etc., for drugs with greater than five recipients requesting the brand. The majority of requests were for anticonvulsants; other requests included branded narcotics, Synthroid® and immunosuppressants. More data is needed to report meaningful results. 90% of approvals were based on criteria C. (In the prescriber’s opinion, transition to generic alternative would represent an unacceptable risk to the patient). The second most commonly used rationale was Criteria A.1. (therapeutic failure to the generic).

Dr. Oesterman requested that in addition to tracking and monitoring the PA data for the DAW-1 edit, a report on the number of claims for anticonvulsants in patients who have a diagnosis of a seizure disorder. He expressed concern regarding criteria C stating that once more data is available, revisit the criteria.

Dr. Marx felt that criteria A and B should be reconsidered particularly regarding the submission of the MedWatch form which most prescribers will probably not comply with. The term “unacceptable risk” in criteria C is probably the wrong verbiage; it’s rarely an “unacceptable risk” but may be an “undesirable risk”. Approval for branded Percocet® or Lortab® seems pointless unless there was an issue with the dye component. To only have eleven denials requires a fair amount of infrastructure to deny those cases.

Ms. Lawrence stated that what prompted this request to the DUR Board was the data in the pharmacy system which indicated a high utilization of the DAW-1. What may be beneficial is for Magellan to determine if there was a significant decrease in the utilization of the DAW-1 and overrides.

Keith Macdonald suggested that if a request for a particular drug is always approved; remove it from the DAW list.

- c. Discussion and Action by Board on the Update and Presentation of the Dispense as Written (DAW = 1) Edit

Dr. Oesterman proposed tabling action until more data is collected during the next quarter and presented at the next meeting. The Board agreed.

ix. Update and Presentation on Psychotropic Medications for Children and Adolescents Edit

a. Public Comment

Public comment was taken out of order during discussion in item c.

b. Discussion by Board

Ms. Lawrence stated that the edit is broken down into two age groups, 0-5 years old and 6-17 years. The medications included are anti-anxiety agents, antidepressants, lithium preparations, anticonvulsants, antipsychotics and sedatives. This policy does not include treatment for ADD/ADHD which is outlined in a separate policy. An ICD-9 on the claim for seizure disorder will bypass the PA requirement for anticonvulsants. Prior authorization is required for all psychotropic medications for recipients 5 years and younger requiring a specific diagnosis or symptom for the specific medication, a comprehensive treatment plan and physician monitoring. Patients receiving more than one agent must have failed a single agent treatment in one therapeutic class and is being changed to a new agent within the class; or has failed a single agent and requires treatment with two agents within the class; or an additional agent is being used to treat a new diagnosis, unique symptom or side effect.

She referred to the table which compares data before and after implementation of the edit clarifying that recipients are categorized into two eligibility groups, Other and Welfare (children in State custody). The impact of the edit has been positive.

- ADHD Agents: No change; criteria is addressed in a separate policy.
- Antidepressants 0-5 years:
Welfare: recipients decreased from 46 to 18; claims from 98 to 35 for an average claims per recipient of 2.1 before the change to 1.9.
Other: recipients decreased from 36 to 22; claims 60 to 38 with average claims per recipient remaining neutral.
- Antipsychotics 0-5 years:
Welfare: recipients decreased from 91 to 66; claims from 323 to 193 with average claims per recipient of 3.5 before the change to 2.9.
Other: recipients decreased from 103 to 87; claims from 283 to 224 for an average claims per recipient of 2.7 before the change to 2.6.
- Anticonvulsants increased which may be attributed to the implementation of the ICD-9 on the claim for seizure disorder to bypass the PA requirement increasing access. Increasing access to the right population is considered a positive action.
- 6-17 years of age: no change in utilization. The policy for this age group does not require a PA up front if a claim was received for the medication within the past 30 days.

Ms. Lawrence stated that overutilization of psychotropic medication in children is currently a large national issue. DHCFP supports further management of psychotropic medications for children and proposed that the Board could consider applying the policy of the 0-5 age group to the 6-17 year olds. She offered to bring back more data, case studies, FDA indications for the drugs within the classes to assist the Board in making a determination. Another option would be to further manage the agents for ADD/ADHD by classifying them as psychotropic medications. A report on the utilization of psychotropic medications indicated that Nevada is one of a few states that these medications are being prescribed by a psychiatrist and not a general practitioner.

Education of this policy targets psychiatrists. She added that there has been no public outcry or negative effects due to this policy.

c. Discussion and Action by Board on the Update and Presentation of Psychotropic Medications for Children and Adolescents Edit

Dr. Oesterman stated that it is rewarding to see that a positive impact is being made in the 0-5 year old age group. He asked the Board to review the criteria and consider expanding the policy to the 6-17 year old group.

Ms. Lawrence stated that a child psychiatrist, a psychiatrist on the Board, and a general psychiatrist assisted in the development of this policy and there was overall agreement that due to the sensitivity of the developmental brain of a 0-5 year old, use of these medications is of more concern in this age group. The agreement was to require prior authorization up front for this population.

Dr. England suggested that the same criteria should be applied across the board to both age groups.

Dr. Marx expressed concern that some of these drug classes have abuse potential. He suggested consideration be given to require compliance testing to verify that the medication is actually given to the patient and not being diverted to an illicit market.

Dr. Oesterman accepted public comment from Jim Wilkes, Calloway Labs. Mr. Wilkes said that he is here at the request of one of the Board members. He stated that his company is willing to help facilitate a program regarding diversion of these medications. Prescription pain relievers are the new drug users' drug of choice exceeding marijuana or cocaine. Opioid painkillers cause more drug overdose deaths than cocaine and heroin combined. Methods of acquiring prescription drugs for abuse include doctor-shopping. The DEA works closely with the medical community to help them recognize drug abuse and signs of diversion and relies on their input and due diligence to combat diversion. Prescription drug abuse problems may occur in patients, their families and friends. Diversion may be intentional/unintentional by the patient or stolen from the patient. Urine compliance testing (UCT) is the standard of care to identify patient compliance. Calloway Labs in conjunction with UCLA has developed a prescription monitoring and risk management strategy which has shown to have driven down the number of inconsistent results that clinicians see when they are monitoring patients.

Keith Macdonald said that two of the most commonly abused medications within this drug class (antidepressants and sedatives) are currently monitored by the Controlled Substance Abuse Prevention Task Force and Medicaid controlled substance drug utilization data is available through the task force. He asked Dr. Marx regarding abuse in the other drugs being discussed.

Dr. Marx replied that there is abuse particularly with the anti-anxiety drugs and ADD/ADHD agents. He expressed concern regarding the legitimate source of these medications for patients with no legitimate need.

Mr. Wilkes commented that the abuse of the ADD/ADHD drugs has increased exponentially over the past four years and is the most popular drug abused on college campuses across the country and also being used for weight loss.

Ms. Lawrence reminded the Board of the lock-in program currently in place. DHCFP works with the Controlled Substance Abuse Prevention Task Force utilizing both the task force's data and the State's data when determining patients for lock-in. Lock-in is not restricted to controlled substances.

MOTION: David England motioned to apply the 0-5 year old criteria to the 6-17 year old group.

Keith Macdonald stated that he would like to have input from the practitioners that care for these children. Because of the time involved in obtaining PAs, he would like information on the impact this has on them.

Dr. Marx stated that the PA process does have a place and is valuable in the case of psychotropic drugs but would like to defer action pending input from the psychiatrist member of the Board.

Dave Wuest stated that the PA is not tied to a physician or particular pharmacy, but to the recipient and drug. The PA for a particular drug will be in place for the length of approval even if there is a change in physician or pharmacy. In addition, any change to this policy is required to be presented at public hearing.

Ms. Lawrence said that this policy was developed in conjunction with a group of child psychiatrists and all were in agreement. The psychiatrists were Medicaid providers but not the top prescribers of these medications. The group noted that the high utilization of these agents for 0-5 year olds was out of the norm. The edit has dramatically decreased utilization appropriately in the 0-5 population which was the intent of the policy. There is no management in the 6-17 year group so the proposal is to apply the 0-5 year old criteria to the 6-17 requiring documentation on a PA that there is a symptom or diagnosis being treated and to also address polypharmacy of these agents documenting why there is more than one drug being prescribed within the class.

SECOND: James Marx

VOTES: Unanimous

MOTION CARRIED

x. Review of Existing Prior Approval Criteria for Synagis®

a. Public Comment

Ann Marie Licos, MedImmune, spoke in support of Synagis®. She requested the Board consider changes to the proposed Synagis® criteria so that they are in accordance with FDA approved label use and consistent in the manner in which Synagis® has been studied. The IMPact Trial was presented to the FDA and is included in the package insert. The study population consisted of premature infants six months old or younger at the start of the RSV season and patients with bronchopulmonary disease less than 24 months old. The Synagis® group had a 55% reduction in RSV hospitalization compared to the placebo group. She referred to section d. in the proposed criteria which addresses infants born at 32 to 35 weeks, born less than 3 months at the start of RSV season and only lists two risk factors. IMPact Trial patients were less than 6 months prior to the start of RSV season. The proposed criteria would eliminate infants 3-6 months old at the beginning of RSV season as eligible for Synagis®. There are over a dozen risk factors published which increase an infant's risk for RSV including school aged siblings, exposure to tobacco smoke, crowded living conditions, and low birth weight; she requested the risks not be limited to the two in the criteria. In the IMPact Trial, 5 doses were given throughout the RSV season; the proposed criteria only allow one, two or three doses. CID guidelines published in the American Academy of Pediatrics Red Book 2009, and guidelines recently published by the National Perinatal Association in 2010, include dosing Synagis® between 32 and 35 week infants. She encouraged the Board to consider changing the guidelines to reflect dosing in all "eligible high risk patients" per the FDA approved labeling and several risk factors.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Synagis®

Dr. Oesterman noted that Dr. Craig Nakamura, Board Certified Pediatric Pulmonologist, has submitted a letter of testimony on Synagis® for Board consideration.

Dr. Townsend stated that the current policy which the Board has adopted was based on recommendations of the previous American Academy of Pediatrics Committee on Infectious Diseases and Committee on Fetus and Newborn Pediatrics. The current Synagis criteria require that the patient be less than two years of age. The goal of the proposed criteria is to provide prophylaxis for RSV children at high risk consistent with the updated American Academy of Pediatrics Policy published in December 2009 and consistent with criteria used by other state Medicaid programs. The overall goal is to provide appropriate and cost-effective prophylaxis against RSV to decrease hospitalization. Synagis® is administered at 15mg/kg once every 30 days during the established RSV season. Use outside of the season is not cost-effective nor does it provide benefit to the recipients per AAP guidelines (included in meeting packet). There is no data that has shown a decrease in RSV associated mortality or morbidity (recurrent wheezing following infection). Use of Synagis® outside of the proposed guidelines will require a PA request with supporting documentation. Based on current AAP guidelines, the proposed changes are:

- d. Infants born at 32 to less than 35 weeks of gestation (defined as 32 weeks, 0 days through 34 weeks, 6 days) born less than 3 months before the start of the RSV season or born at any time throughout the RSV season with one of the following risk factors:
 - i. Infant attends child care or
 - ii. One or more children younger than 5 years live permanently in the child's household.

In addition, the AAP recommends that a maximum of 3 doses be given in this particular population as opposed to 5 doses. Dr Townsend referred to sections in the published AAP Policy discussing both the risk factors for hospitalization and the number of doses recommended.

She noted that the dates for RSV season in the proposed policy presented in the binder are incorrect for the current window. Initiation and termination dates for coverage of prophylaxis are modified annually to reflect current CDC definitions of the RSV season (MMWR). According to the Centers for Disease Control and Prevention (CDC), RSV season in Nevada starts November 15 and ends March 31.

Dr. Oesterman asked for clarification for anything outside of these guidelines, a PA may be submitted with supporting medical justification and Dr. Townsend replied that is correct.

Mr. Lither referred to section ii "...live permanently in the child's household." and asked how "permanently" is defined. Dr. Townsend replied full time resident including children who split their time between two households; e.g., divorced parents.

Dr. Marx asked regarding variance from the manufacturer's PI. Dr. Townsend responded that the PI is frequently followed but updated medical information is also considered.

Dr. Marx referred to Dr. Nakamura's comment in his letter that RSV season occurs earlier and tends to be longer in Nevada and asked how that impacts the recommendations. Ms. Lawrence responded that the chapter policy presented is inaccurate and has been modified to say that RSV season is in accordance the CDC season for Nevada; timeframes will not be stated in the policy. DHCFP works with Dr. Nakamura every year providing exceptions on an administrative level to his patients that may fall outside of the guidelines with this policy and other issues as well.

Ms. Lawrence stated in reviewing list serves, the majority of other states have aligned with the AAP guidelines versus the PI.

MOTION: James Marx motioned to approve the revised Synagis® criteria to be consistent with the AAP guidelines.

SECOND: Keith Macdonald

Dr. Marx commented that in view of the fact that exceptions can be made and readily granted, he is comfortable with the guidelines as stated.

VOTES: Unanimous

MOTION CARRIED

xi. Proposed Prior Approval Criteria for Topical Androgens

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Topical Androgens

Dr. Townsend stated that the intent of the criteria is to discourage off-label use and abuse of these products for both safety and cost issues. The abuse of these products is significant and there are medical consequences as a result. She reviewed the proposed criteria which are based on guidelines of the Endocrine Society (included in the meeting binder). The criteria will apply to preferred and non-preferred products.

MOTION: James Marx motioned to accept the proposed criteria as presented.

SECOND: David England

VOTES: Unanimous

MOTION CARRIED

xii. Proposed Prior Approval Criteria for Ampyra®

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Ampyra®

Dr. Townsend stated that Ampyra® is a selective potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS) as demonstrated by an increase in walk speed. It is thought to improve action potential conduction in demyelinated nerves although the mechanism of action has not been fully delineated. This drug has a long history of use in the United States prior to approval by the FDA. It's been compounded from chemical sources and used off-label for over 20 years for various types of neurological conditions without substantial evidence of efficacy. There is a large potential for off-label use of this very expensive product. It also has a significant adverse event profile. The approved product is an extended release formulation which differs from what's been compounded in the past with immediate release resulting in higher peaks and higher risk of seizures. The dose is 10mg twice per day. Higher doses have not shown to be more effective and not recommended due to higher risk of seizure including generalized tonic-clonic seizures. It's contraindicated in patients with history of seizures, moderate to severe renal impairment and in pregnancy due to the potential for fetal harm. She noted that I.H. was inadvertently left off and should state "Patient is not Pregnant". Study inclusion criteria included the ability to walk 25 feet in 8 to 45 seconds. In study 1 a response was achieved in 34.8% of patients receiving Ampyra® versus 8% placebo; the median change was 0.5 feet per second. In study two, the response rate was 43% versus 9%. Other endpoints were summarized. In summary, there was modest improvement in walk speed in the minority of patients taking this drug during the clinical trials. She presented the proposed criteria stating that the intent is to provide Ampyra® to patients where it's been demonstrated to be efficacious. Initial duration of approval for patients meeting criteria will be 12 weeks. Renewal of the PA will require that the patient continues to meet criteria and demonstrate improvement in

timed walking of at least 20%; duration of approval will be one year. Quantity limit is 60 10mg tablets per 30 days.

Dr. Oesterman asked how many MS patients are on Medicaid and if this agent is used concurrently with other MS products. Dr. Townsend stated that this is add-on therapy; 65% of patients in the clinical trials were taking a disease modifying agent (e.g., interferon or copaxone). It's not a requirement that patients be on a disease modifying drug. Ampyra® does not affect disease progression.

MOTION: Keith Macdonald motioned to approve the proposed criteria for Ampyra® and to add criterion 1.H. Patient is not pregnant.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

MOTION: Keith Macdonald motioned to approve the quantity limit of 60 10mg tablets per 30 days.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

xiii. Public Comment

Jim Wilkes, Calloway Labs, suggested that the Board consider routine monitoring within 30 days to be a requirement for approval of a PA for some medications which may be diverted to the street. He offered to partner with the Medicaid risk management group to investigate and develop prescription monitoring in this program.

Keith Macdonald asked if there is data available based on the request for PAs in terms of how many are done at the time of the prescribing or done post-prescribing when the patient is told that it requires a PA by a provider. His concern is with the cost impact of PAs in general as well as the tamperproof prescription requirement. In spite of the time that has lapsed since the tamperproof requirement was implemented, non-tamperproof prescriptions continue to be used requiring a call to the prescriber. Dave Wuest stated that the system can track when a product comes into the pharmacy system and doesn't have a PA. The difficulty is if the subsequent prescription comes in and the prescription number or the drug has changed. It would be ideal if the prescriber obtained a PA at the time the prescription is written which would save time. Data can be provided on the number of drugs that are submitted that require a PA and the number that have a PA in place.

Ms. Lawrence offered to provide updates to the Board on health information technology within the agency. Health information technology updates will be agendaized for future meetings.

xiv. Date and Location of Next Meeting

The next meeting is scheduled for October 28, 2010, at the Grant Sawyer Building in Las Vegas with videoconferencing to the Nevada State Legislature Building in Carson City.

xv. Adjourn

Chairman Oesterman adjourned the meeting at 3:34 p.m.